ANDA 74-651

JUL 16 1997

Lemmon Company
Attention: Deborah A. Jaskot
650 Cathill Road
Sellersville, PA 18960

Dear Madam:

This is in reference to your abbreviated new drug application dated March 24, 1995, submitted pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetic Act, for Terazosin Hydrochloride Tablets, 1 mg (base), 2 mg (base), 5 mg (base) and 10 mg (base).

Reference is also made to your amendments dated November 5 and November 19, 1996 (2); and February 24, March 20, April 9, and July 15, 1997.

We have completed the review of this abbreviated application and have concluded that, based upon the information you have presented to date, the drug is safe and effective for use as recommended in the submitted labeling. Therefore, the application is **tentatively approved.** This determination is based upon information available to the Agency at this time, which includes information in your application and the status of current good manufacturing practices of the facilities used in the manufacturing and testing of the drug products. Therefore, this determination is subject to change on the basis of new information that may come to our attention. This letter does not address notice issues related to the 180-day exclusivity provisions under section 505(j)(4)(B)(iv) of the Act.

The reference listed drug product upon which you based your application is subject to a period of patent protection and therefore, final approval of your application may not be made effective pursuant to 21 U.S.C. 355 (j)(4)(B)(ii), until the period has expired, i.e., April 29, 2013 (Patent No. 5,294,615).

Please provide the Agency, at least 30, but not more than 90 days prior to April 29, 2013, an amendment to this application. This amendment should identify changes, if any, in the conditions under which the product was tentatively approved and should include updated information such as labeling, chemistry, manufacturing, and controls data as appropriate. This submission should be designated as a MINOR AMENDMENT in your cover letter. In addition to, or instead of, the amendment requested above, the Agency may, at any time prior to the final date of approval, request that you submit an amendment containing the information described above.

Failure to submit such an amendment requested by the Agency will prompt a review of the application which may result in rescission of this tentative approval letter.

Any significant change in the conditions outlined in this abbreviated application requires Agency approval before the change may be made effective.

Prior to the issuance of a final approval letter by the Agency your product is not to be deemed approved for marketing under 21 U.S.C. 355 and not to be listed in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, published by the Agency. Should you believe that there are grounds for issuing the final approval letter prior to April 29, 2013, you should amend your application accordingly.

At the time you submit any amendments, you should contact Ms. Sheila M. O'Keefe, Project Manager, at (301) 827-5848, for further instructions.

The introduction or delivery for introduction into interstate commerce of the drug before the effective approval date is prohibited under 21 U.S.C. 311(d).

Sincerely yours,

Douglas L. Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research